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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,066	12/03/2003	Athur C. Perry	1987.1-7 (040020)	7966
24243	7590	02/03/2006	EXAMINER	
CHARMASSON, BUCHACA & LEACH, LLP 1545 HOTEL CIRCLE SOUTH, SUITE 150 SAN DIEGO, CA 92108-3426			BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 02/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,066

Applicant(s)

PERRY ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 12-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election of **Implant: Species A** (Figure 1), **Die Press: Species A** (Figure 7), and **Indicia: Species B** (color coding) in the reply filed on June 30, 2005 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 11 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 30, 2005.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

a. Correction of the following is required: "wherein said passageway has a diameter selected so that an upper lip of said coating surrounding said passageway is positioned a radial distance greater than any portion of said implant in communication with said passageway" (see claim 16, lines 2-6).

Claim Objections

4. Claims 4-6, 20, 22, 25, and 27 are objected to because of the following informalities:

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- a. Regarding claim 4, please substitute (i) “The implant” (see line 1) with --The coating--; (ii) “polycaprolactone” (see line 3) with --polycaprolactone--; and (iii) polyorthoester (see line 4) with --polyorthoester--. Appropriate correction is required.
- b. Regarding claim 5, please substitute “The implant” (see line 1) with --The coating--.
Appropriate correction is required.
- c. Regarding claim 6, please substitute (i) “The implant” (see line 1) with --The coating--; and (ii) “from a group” (see line 2) with --from the group--. Appropriate correction is required.
- d. Regarding claim 20, please (i) add --said coating-- in front of “having a first portion” (see line 4); and (ii) substitute “bioabsorbility” (see line 4) with --bioabsorbability--. Appropriate correction is required.
- e. Regarding claim 22, please substitute “comprises” (see line 1) with --comprising--.
Appropriate correction is required.
- f. Regarding claim 25, please substitute (i) “polycaprolactone” (see line 3) with --polycaprolactone--; and (ii) polyorthoester (see line 4) with --polyorthoester--. Appropriate correction is required.
- g. Regarding claim 27, please substitute “from a group” (see line 2) with --from the group--.
Appropriate correction is required.

Drawings

- 5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

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a. Therefore, the “passageway has a diameter selected so that an upper lip of said coating surrounding said passageway is positioned a radial distance greater than any portion of said implant in communication with said passageway” (see claim 16, lines 2-6) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

b. Therefore, the “first portion comprises two concentrically adjacent layers” (see claim 17, lines 1-2) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 18 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a. Regarding claim 18, the “means for reducing an adverse immune response” (see line 2) is not enabling. The specification does not disclose/describe a structure (means) that will perform (for) the function (reducing an adverse immune response) as required in claim 18.

b. Regarding claim 23, the “means for reducing an adverse immune response” (see line 2) is not enabling. The specification does not disclose/describe a structure (means) that will perform (for) the function (reducing an adverse immune response) as required in claim 23.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 16, the limitation “said passageway has a diameter selected so that an upper lip of said coating surrounding said passageway is positioned a radial distance greater than any portion of said implant in communication with said passageway” (see lines 2-6) is vague and

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confusing, rendering claim 16 indefinite. By “radial distance”, is it referring to the thickness (i.e., a radial distance) of coating 4? If that is the case, it doesn’t seem (from the Figures) that rim 14 is positioned a “distance greater than any portion of said implant in communication with said passageway”.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-10 and 12-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Perry (WO 94/14390 A1).

Referring to Figures 1, 3, and 4, Perry discloses an orbital implant comprising:

- (i) a substantially spheroid body *sized and shaped to be placed* (emphasis added to functional language) in the orbit;
- (ii) a coating (“coated” or “wrapped”: see page 5, lines 23-29; page 13, line 34 to page 14, line 2) *sized and shaped to intimately contact* (emphasis added to functional language) a section of said body; and wherein said coating has a first portion having a first bioabsorbability and a second portion having a second bioabsorbability different from said first bioabsorbability. The orbital implant may be coated/impregnated with a first bioabsorbable portion/material (e.g., a vascularization agent) prior to (see page 16, lines 31-35; page 17, lines 4-6) or after (see page 17, lines 7-13) applying a second bioabsorbable portion/material (e.g., collagen, polyglycolic acid, or

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polylactic acid coating/wrapping), which subject matter is not only well known in the art but is further disclosed at page 22, lines 4-14. Chemical and/or molecular bonds keep said first and second portions/materials bonded.

The bioabsorbable (see page 12, lines 5-26) coating/wrapping materials are disclosed as not causing undue adverse immune response (see page 11, lines 19-24). The coating/wrapping may further include therapeutic agents (see page 13, lines 7-8; page 14, lines 14-29), color-coding indicia (see page 22, lines 15-18), passageways *sized to allow* (emphasis added to functional language) fluid exchange therethrough (see page 16, lines 25-29; page 23, lines 34-37; page 28, lines 19-23), a surface having microtexturing (see page 14, lines 31-36; page 24, lines 14-15) and/or an outer surface which is smoother than a first surface (see page 12, lines 27-29; page 14, lines 31-36; page 24, lines 15-17), a thickness of less than one millimeter (see page 12, lines 27-29), and a thickness *selected to allow melting penetration* (emphasis added to functional language) using a handheld cautery (see page 29, lines 11-14).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Stafford (US 3,364,501), Vachet (US 5,089,021), Martinez (US 5,584,880), and Hicks et al. (US 6,346,121).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

September 15, 2005

A large, stylized handwritten signature in black ink, consisting of a large loop followed by a vertical stroke and a horizontal stroke.A handwritten signature in black ink, consisting of a large 'C' followed by a 'Z'.

**CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**